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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,760	07/31/2001	Paul Douglas Scotti	514274-2001	6462

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EXAMINER

PAK, YONG D

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 12/17/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/868,760	<b>Applicant(s)</b> SCOTTI ET AL.	
	<b>Examiner</b> Yong Pak	<b>Art Unit</b> 1652	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 November 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 1-8, 11, 12 (partially), 13 (partially) and 14-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |                                                                                                              |                                                                             |
|--------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>9</u> . | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

This application is a 371 of PCT/NZ99/00227.

Claims 1-24 are pending.

### ***Election/Restrictions***

Applicant's election with traverse of Group II and a further election of SEQ ID NO:6 in Paper No. 12 is acknowledged. The traversal is on the ground(s) that the polynucleotide of Group II encodes the polypeptide of Group I. This is not found persuasive because claim 10 of Group II is drawn to DNA encoding a polypeptide of Group I and variants of the DNA. Therefore, a lack of unity exists these variants do not encode the protein of Group II nor fragments of the protein.

Applicants also traverse on the grounds that Group III is a method of making the product of Group I. The examiner disagrees. The method in Group III is drawn to making a protein of 75 kDa. However, the products of Group I encompass short peptides. The methods for purifying or isolating short peptides are very different from the methods used for purifying or isolating proteins. Therefore, a lack of unity exists because Group III is not drawn to a method of making the short peptides of Group I.

Applicants also traverse the restriction requirement between the different polypeptides and polynucleotides on the grounds that the products represent members of a structurally and functionally related genus. The examiner disagrees because the products have different structures and different functions, such different physical and chemical properties.

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The requirement is still deemed proper and is therefore made FINAL.

Claims 1-8, 11, 12 (partially), 13 (partially) and 14-24 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 12.

### ***Claim Objections***

Claim 9 is objected to as being dependent upon a non-elected base claim, and should be rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 9-10 and 12-13 are objected for being drawn to non-elected products.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-10 and 12-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 9 has been interpreted to include all the limitations of its base claim and any intervening claims.

Claim 9 is dependent on claims 2-3, which are drawn to polypeptides of unknown function and little structure. Claim 9 is also dependent on claim 7, which is drawn to polypeptide of unknown structure. Claims 9-10 and 12-13 are drawn to DNA encoding SEQ ID NO:6, active fragments and variants. Therefore, these claims are drawn to a genus of DNA, with any structure, function and/or from any source.

The specification does not contain any disclosure of the structure and function of all DNA fragments of SEQ ID NO:6 or portions thereof. The genus of DNA that comprise these above fragments and portions of SEQ ID NO:6 is a large variable genus with the potentiality of encoding many different proteins. Therefore, many structurally and functionally unrelated DNA are encompassed within the scope of these claims, including partial DNA sequences. The specification fails to describe any other representative species by any identifying characteristics or properties other than being a variant or fragment of SEQ ID NO:6 and fails to provide any structure: function correlation present in all members of the claimed genus.

Therefore, the specification is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Claims 9-10 and 12-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for DNA of SEQ ID NO:6, does not reasonably provide enablement for DNA fragments and variants of unknown structure

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and or function. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, how to make the invention commensurate in scope with these claims.

Factors to be in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) considered in determining whether undue experimentation is required, are summarized the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claims are drawn to DNA fragments of SEQ ID NO:6 having unlimited structure encoding a polypeptide with no or unknown activity. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of constructs broadly encompassed by the claims. Therefore, the breadth of these claims is much larger than the scope enable by the specification.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen a large number of possible combinations .

The predictability as to the level of conservation between the disclosed sequences and those of other serine phosphatase inhibitors is extremely complex. While recombinant techniques are available, it is not routine in the art to screen large numbers of amino acids where the expectation of obtaining similar sequences is unpredictable. The amino acid sequence determines the structural and functional properties of an enzyme. Knowledge of which sequences can be altered or removed

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and still result in similar protein activity is well outside the realm of routine experimentation.

Therefore, one of ordinary skill would require guidance in order to make fragments or variants of SEQ ID NO:6 having unknown function in a manner reasonable correlated with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10 and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Pannetier et al.

Pannetier et al. (U.S. Patent No. 5,747,246) teach a DNA molecule that is a variant of SEQ ID NO:6 (SEQ ID NO: 23, Columns 29-30 ). Pannetier et al. also teach a vector and a host cell comprising said DNA (Columns 15-16). Therefore, the teachings of Pannetier et al. anticipates claims 10 and 12-13.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on 8:00 A.M. to 4:30 P.M weekdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned

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are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak  
Patent Examiner

December 12, 2002

  
PONNATHAPACHUT MURTHY  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1000